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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/588,558	05/25/2007	Nicolas Peter Shortis	17811US01	8274

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EXAMINER	
SPIVACK, PHYLLIS G	

ART UNIT	PAPER NUMBER
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/588,558	SHORTIS, NICOLAS PETER	
	Examiner	Art Unit	
	Phyllis G. Spivack	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *03 December 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Applicant's Response filed December 3, 2008 to the Election Requirement mailed November 3, 2008 is acknowledged. Applicant elected irritable bowel syndrome without traverse.

Accordingly, the subject matter currently under consideration are those methods of treating irritable bowel syndrome comprising administering balsalazide, or a salt thereof, or a composition comprising balsalazide, claims 1-10, as well as methods drawn to administering 4-aminosalicylic acid or 5-aminosalicyclic acid modified to include a 4-aminobenzoyl-β-alanine, or a composition comprising the compound, claim 11. Those methods drawn to the treatment of conditions other than irritable bowel syndrome are presently withdrawn from consideration by the Examiner, 37 CFR 1.142(b), as drawn to non-elected inventions.

A Response filed August 1, 2008 and Supplemental Remarks filed August 14, 2008 are further acknowledged. Claims 12 and 13 are canceled. Claims 1-11 remain under consideration.

Those rejections set forth in prior Office Actions that are not herein reiterated are withdrawn. The following rejections are the only rejections presently applied to the instant claims.

Claim 1-11 were rejected under 35 U.S.C. 112, first paragraph, in the last Office Action, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention. The claims are presently directed to the prophylaxis or treatment of irritable bowel syndrome. It was asserted the specification

does not reasonably provide enablement for methods of prophylaxis within the full scope of the claims.

Applicant argues the last Office Action acknowledged that the specification provides enabling support for the prophylaxis of irritable bowel syndrome on page 7.

No such acknowledgement is noted on page 7 or anywhere in the Office Action. In the last paragraph on page 7, the Office Action states that clear support is provided only for irritable bowel syndrome. The sentence immediately prior states support for preventing any bowel disease or disorder is absent. Accordingly, Applicant has misinterpreted the statement in the last Office Action. On pages 10-12 of the specification, testimonial Examples 1-3 are described wherein each of the three patients are suffering from either diarrhea-predominant irritable bowel syndrome or intermittent diarrhea/constipation irritable bowel syndrome. The present disclosure is clearly not predictable for prevention of any disorder. The disclosure is not commensurate in scope with the instant claims.

The rejection of claims 1-11 under 35 U.S.C. 112, first paragraph, is maintained since to practice the claimed invention would require a person of ordinary skill in the art to engage in undue experimentation with no assurance of success.

Claim 11 was rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 4, 8 and 9 of U.S. Patent No. 5,519,014, in the last Office Action. The claims of the patent are drawn to treating irritable bowel syndrome comprising administering a derivative of salicylic acid that is 4-aminosalicylic acid. See claim 9. Instant claim 11 is drawn to the administration of 4-

aminosalicylic acid **or** 5-aminosalicylic acid compound modified to include a 4-aminobenzoyl-β-alanine.

Claims 1-10 were rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson et al., WO 2005/030173, in the last Office Action. It was asserted Wilson teaches the administration of a colon-specific drug delivery system using interpolymer complexations of agents having a core of pharmaceutically active agent(s). See the Abstract. Those colon diseases encompassed by Wilson's teaching include irritable bowel syndrome (page 1, line 29). See the last paragraph on page 3, where more than one active ingredient may be employed, as required by instant claim10. Among those active agents contemplated are balsalazide, olsalazine, mesalamine (5-aminosalicylic acid), sulfasalazine, ipsalazide, the antibiotic metronidazole and anticholinergics. Also see claim 3, page 15.

Applicant questions the status of Wilson as prior art.

The international filing date of Wilson is September 24, 2004. WO 2005/030173 is published in English and designates the United States. The 102(e) date is the international filing date. However, a benefit to the provisional application filed September 25, 2003 is proper.

Applicant further argues no specific teaching drawn to the use of balsalazide to treat non-inflammatory bowel diseases is found in Wilson.

Treatment of irritable bowel syndrome is clearly encompassed in Wilson's teaching. See claim 25, page 18, as well as claim 3, page 15, where balsalazide is included among multiple drugs that may be administered in Wilson's teaching.

The rejection of claims 1-10, of record, under 35 U.S.C. 103 is maintained.

In the last Office Action claim 11 was rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson et al., WO 2005/030173, in view of Lin et al., U.S. Patent 6,326,364. It was asserted Lin teaches the administration of such derivatives that are conjugated dosage forms wherein, for example, a 5-aminosalicylic acid moiety, or a 5-amino salicylate moiety, is conjugated to another 5-amino aminosalicylic acid moiety or a 5-amino salicylate moiety. Balsalazide is specifically recited as a preferred conjugated 5-aminosalicylate compound. See column 8, lines 8-31. The administration may be to a human.

In view of the combined teachings of Wilson and Lin, one skilled in the gastroenterology art would have been motivated to prepare a dosage form comprising a conjugate of a 5-ASA compound modified to include a 4-ABA side chain for administration to a mammal to treat irritable bowel syndrome. Balsalazide is 5-aminosalicylic acid modified to include 4-aminobenzoyl-β-alanine.

The rejection of claim 11 under 35 U.S.C. 103(a) as being unpatentable over Wilson et al., WO 2005/030173, in view of Lin et al., U.S. Patent 6,326,364, is maintained.

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this Final Action is set to expire THREE MONTHS from the mailing date of this Action. In the event a first reply is filed within TWO MONTHS of the mailing date of this Final Action and the Advisory Action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the Advisory Action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the Advisory Action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this Final Action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached on 10:30 AM-7 PM.

If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Ardin Marschel, may be reached on 591-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

March 9, 2009

/Phyllis G. Spivack/
Primary Examiner, Art Unit 1614